

REMARKS

Claims 1-63 are pending. Claims 1-36 and 62 have been withdrawn from consideration.¹ Claim 60 has been canceled. Claim 64 has been added. Claims 37, 39, 45-49, 51-54, 58, 59, and 61 have been amended. Support for the claims as amended can be found in the claims as filed, and throughout the specification, for example on page 10. Accordingly, claims 37-59, 61 and 63 will be pending after the above amendments have been entered.

Applicants do not concur with the Examiner's indication that it would be overly burdensome to search all of the claims in Group I and Group II. However, in order to advance prosecution of the present application, Applicants will continue to prosecute Group II. Accordingly, claims 1-36 and 62 above have been canceled.

Applicants submit herewith copies of the references CW, DN, EJ, GI, GM, HK, HM-HO, and ID, which the Office Action indicated were unavailable to the Examiner. Applicants respectfully request that the Examiner consider these references and so indicate on the accompanying PTO form 1449. Applicants also request that the Examiner indicate on the form PTO-1449 that references LH, Application Serial No. 08/465,880, which issued as U.S. Patent No. 5,955,589; LI, Application Serial No. 08/468,037, which issued as U.S. Patent No. 5,859,221 also were considered, as stated in the Office Action. Applicants further request that the Examiner consider reference LN, application Serial No. 09/044,506, which issued as U.S. Patent No. 5,955,443.

¹ Applicants note that the Office Action summary states that Claims 54-57 and 59-61 were objected to, but that Claim 61 is rejected under 35 U.S.C. § 112, first and second paragraph, and claims 59-61 are rejected under 35 U.S.C. § 102 and 35 U.S.C. § 103.

In addition, Applicants respectfully request consideration of the following references, which are believed to be available to the Examiner: Reference LJ, application Serial No. 08/762,588, issued as U.S. Patent No. 5,750,692; reference LK, application Serial No. 08/777,266, issued as U.S. Patent No. 6,077,833; reference LM, application Serial No. 09/016,520, issued as U.S. Patent No. 6,127,533; and reference LO, application Serial No. 09/062,416, issued as U.S. Patent No. 6,111,094.

Applicants have amended reference AC to read "Retrieved from the Internet: <URL: www.paddocklabs.com/secundum/secaindx.html >- - according to the requirements of MPEP §707.05(e).

The Office Action states that the Declaration filed September 3, 1999, is allegedly defective. Applicants submit herewith a Substitute Declaration.

Applicants have amended the reference on page 22, lines 19-32 to correct an inadvertent clerical error and to refer to the correct U.S. Patent application number, 08/762,588.

Applicants have amended the specification to refer to the electronic document in the form required by MPEP section 707.05(e).

Claims 54-57 and 59-61 are objected to as being dependent on nonelected base claim 1. In response, Applicants have amended claims 54, 59 and 61 to be in independent form by incorporating the language of claim 1, as suggested by the Office Action. Therefore, Applicants respectfully request reconsideration and withdrawal of the objection.

Claim 59 stands objected to as allegedly being identical to claim 60. Claim 60 has been canceled, thereby rendering the rejection moot.

Claims 37-61 stand provisionally rejected under 35 U.S.C. § 101 as allegedly claiming the same invention as that of claims 37-61 of copending application serial no. 09/083,586. Since the rejection is provisional in nature, Applicants will address the rejection when there is an indication of otherwise allowable subject matter in the present application.

Claims 37, 42 and 44-61 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over copending claims 30-46 and 50-53 of copending application serial no. 09/083,585. Since the rejection is provisional in nature, Applicants will address the rejection when there is an indication of otherwise allowable subject matter in the present application.

Claims 37, 42 and 44-61 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 30-46 and 50-53 of co-pending application serial no. 09/315,581. Since the rejection is provisional in nature, Applicants will address the rejection when there is an indication of otherwise allowable subject matter in the present application.

Rejection under 35 U.S.C. § 112

Claims 37-51, 53, 58, 61 and 63 stand rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. Applicants respectfully request reconsideration and withdrawal of the rejection in light of the following amendments and arguments.

Claim 37 has been amended at line 1 to recite "an antisense nucleic acid" as suggested by the Office Action. Claim 37 also has been amended to provide proper antecedent basis for the terms "the nucleic acid composition" and "the aerosolized nucleic acid composition."

The Office Action asserts that claim 49 is indefinite in that it is unclear what the phrase "contains more than one oligonucleotide" indicates. However, Applicants respectfully assert that those skilled in the art, having read the present specification and claims, would fully appreciate that the phrase is directed to a composition having more than one oligonucleotide, wherein at least one of those oligonucleotides has the features specifically recited in claim 37; i.e., more than one antisense oligonucleotide wherein the sugar moiety of at least one nucleoside unit of the oligonucleotide is not a 2'-deoxyribofuranosyl sugar moiety, or at least one internucleotide linkage within the oligonucleotide is not a phosphodiester or a phosphorothioate linkage, and wherein the antisense nucleic acid is not directed to an A₁ or A₃ adenosine receptor and is not contained in an expression vector.

Claims 51 and 58 have been amended to recite "an aerosolized solution that consists", and claim 53 has been amended to recite "the role of a gene, " as suggested by the Office Action. The typographical error in claim 61 also has been remedied.

The Office Action further asserts that claim 63 is indefinite for the recitation of the term "ISIS-15839". However, Applicants respectfully direct the Examiner's attention to page 34, line 12 of the specification as originally filed, which provides the sequence denoted by "ISIS-15839." Thus, the term "ISIS-15839" is believed to be sufficiently definite.

Accordingly, the rejection of claims 37-51, 53, 58, 61 and 63 under 35 U.S.C. § 112, paragraph two, are believed to be overcome and should be withdrawn.

Claim 63 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement because the specification allegedly fails to provide a sequence for ISIS-15839. Applicants respectfully direct the Examiner's attention to page 34, line 12 of the specification as originally filed, which provides the sequence denoted by "ISIS-15839." Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejections under 35 U.S.C. § 102 and § 103

Claims 37, 42-48 and 50-61 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by International Application No. WO 96/40266 to Nyce ("Nyce"). However, as amended, each of the present claims recite that the antisense nucleic acid is not directed to an A₁ or A₃ adenosine receptor. Inasmuch as the Nyce does not teach antisense nucleic acids that are not directed to an A₁ or A₃ adenosine receptor, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 102(b).

Claims 37, 42, 44-48, and 50-61 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,641,662 to Debs et al. ("the Debs et al. patent"). However, the claims as amended recite that the antisense nucleic acid is not contained in an expression vector. Inasmuch as Debs et al. do not teach antisense nucleic acids that are not

directed to an expression vector, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 102(b).

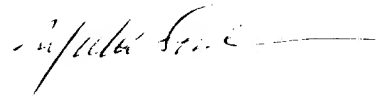
Claims 37-41 and 43 are rejected under 35 U.S.C. § 103(a) for alleged obviousness over either Nyce or Debs et al, alone or in combination with Milligan, J.F, et al., J. Med. Chem. 1993, 36 (14) p. 1923-1937 ("Milligan et al."); U.S. Patent No. 5,789,573 to Baker et al. ("Baker et al."); U.S. Patent No. 5,554,746 to Ravikumar et al., ("Ravikumar et al."), or U.S. Patent No. 5,955,443 to Bennett et al. ("Bennett et al."). However, in view of the discussion above in connection with the rejection under 35 U.S.C. § 102(b), it can be seen that the combination of either of the Nyce or Debs et al. references with any of the Milligan et al., Baker et al., Ravikumar et al., or Bennett et al. references, even if proper (and Applicants assert that such a combination would not be proper), would not render the claimed methods and medical device obvious because those claims recite antisense nucleic acids that have features that are neither disclosed nor suggested by these references. Also, Applicants respectfully submit that even if the combination were to be made, there is no suggestion or motivation to modify the teachings in the references themselves or in the knowledge generally available to one of ordinary skill in the art in order to produce a claimed invention. Applicants therefore respectfully request that this rejection under 35 U.S.C. § 103(a) be withdrawn.

DOCKET NO.: ISIS-3561

PATENT

Applicants respectfully submit that the claims presently before the Examiner patentably define the invention over the applied art and are otherwise in condition for ready allowance.

Respectfully submitted,



Michael P. Straher
Registration No. 38,325

Date: October 24, 2000

WOODCOCK WASHBURN KURTZ
MACKIEWICZ & NORRIS LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215) 568-3100